IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Civil Action No. __

BIODELIVERY SCIENCES INTERNATIONAL, INC., Plaintiff, v. **RECKITT BENCKISER PHARMACEUTICALS, INC.;** **RB PHARMACEUTICALS LIMITED;** and **MONOSOL RX, LLC,** Defendants.	**COMPLAINT** **JURY TRIAL DEMANDED**

BioDelivery Sciences International, Inc. ("BDSI"), for its Complaint against Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Defendants"), alleges as follows:

NATURE OF ACTION

1. BDSI seeks a declaratory judgment of non-infringement and invalidity of U.S. Patent No. 8,475,832 (the "'832 Patent"), U.S. Patent No. 7,897,080 (the "'080 Patent"), and U.S. Patent No. 8,652,378 (the "'378 Patent") pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and the Declaratory Judgment Act, 28, U.S.C. §§ 2201 *et seq.*

PARTIES

2. BDSI is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607.

3. Upon information and belief, Defendant RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

4. Upon information and belief, Defendant RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

5. Upon information and belief, Defendant MonoSol is a Delaware limited liability company having a principal place of business at 30 Technology Drive, Warren, New Jersey.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 2201(a), and 35 U.S.C. §§ 100 *et seq.*

7. This Court has personal jurisdiction over Defendants in North Carolina due to their patent assertion and enforcement activities in North Carolina, including without limitation the filing of Civil Action No. 5:13-760-BO against BDSI and assertion of the '832 Patent. Additionally, this Court has personal jurisdiction over Defendants in North Carolina, because by filing Civil Action No. 5:13-760-BO in North Carolina against BDSI, Defendants have consented to personal jurisdiction in North Carolina for the resolution of any and all patent-related disputes arising between the parties. Further, this Court has personal jurisdiction over Defendants in North Carolina because they have substantial product sales in North Carolina.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

A. The Patents-In-Suit

1. The '832 Patent

9. Upon information and belief, RBP UK holds title (by assignment) to the '832 Patent, entitled "Sublingual and Buccal Film Compositions," issued on July 2, 2013. The '832 Patent is directed generally to film dosage compositions, film formulations, and methods of

treating narcotic dependence. RBP and MonoSol claim to be exclusive licensees of the '832 Patent, and have represented to this Court that they have standing to sue for infringement of the '832 Patent. A true and correct copy of the '832 Patent is attached hereto as Exhibit A.

10. BDSI submitted a petition for *inter partes* review ("IPR") of claims 15-19 of the '832 Patent to the United States Patent and Trademark Office's ("PTO's") Patent Trial and Appeal Board ("PTAB"). The PTAB instituted the requested IPR on July 29, 2014, stating that BDSI established a reasonable likelihood that BDSI would prevail in showing the unpatentability of claims 15-19.

2. The '080 Patent

11. Upon information and belief, MonoSol holds title (by assignment) to the '080 Patent, entitled "Polyethylene-Oxide Based Films and Drug Delivery Systems Made Therefrom," issued on March 1, 2011. The '080 Patent is directed to processes for making a film. Upon information and belief, RBP is an exclusive licensee of the '080 Patent. A true and correct copy of the '080 Patent is attached hereto as Exhibit B.

12. BDSI requested *inter partes* reexamination of all claims of the '080 Patent on September 10, 2012, which the PTO instituted on October 22, 2012. After reviewing the parties' responses to the Office Action and to the Action Closing Prosecution, both of which rejected all of the pending claims in the reexamination of the '080 Patent, the PTO issued a Right of Appeal Notice confirming the rejection of all claims on December 6, 2013. An appeal of the rejection of all claims is currently pending before the PTAB.

3. The '378 Patent

13. Upon information and belief, MonoSol holds title (by assignment) to the '378 Patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," issued on February 18, 2014. The '378 Patent is generally directed to processes

for manufacturing a pharmaceutical film. Upon information and belief, RBP is an exclusive licensee of the '378 Patent. A true and correct copy of the '378 Patent is attached hereto as Exhibit C.

14. On May 21, 2014, BDSI submitted a petition for IPR of all claims of the '378 Patent to the PTAB. The PTAB must decide whether it will institute the requested IPR by December 4, 2014.

B. BDSI Developed BUNAVAIL™ for the Treatment of Narcotic Dependence

15. Defendant RBP is the owner of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film, which is indicated for the treatment of narcotic dependence, which RBP has marketed since 2010. From the early 2000s through mid-2012, RBP marketed a tablet version of Suboxone®.

16. Defendants have previously represented their respective roles in the manufacture and marketing of Suboxone® film as follows: RBP, "with RBP UK's knowledge, has marketed and sold [the Suboxone® film] product in the U.S. since the FDA's approval of the NDA on August 30, 2010…[f]or its part, MonoSol, under a Commercial Exploitation Agreement dated August 15, 2008, has an express exclusive right to manufacture Suboxone® sublingual film for RBP[.]" (*See* D.I. 27 in Civil Action No. 5:13-760-BO (E.D.N.C. filed on January 22, 2014), at 5).

17. For years, BDSI has engaged in extensive research and development efforts geared towards bringing new pharmaceutical products to market in the U.S. and the rest of the world, including a product for the treatment of narcotic dependence.

18. Relevant to this action, on July 31, 2013, BDSI submitted an application pursuant to 21 U.S.C. § 355(b)(2) to the Food and Drug Administration ("FDA") seeking approval to market a new pharmaceutical product, BUNAVAIL™.

19. BUNAVAIL™ is a pharmaceutical product for the treatment of narcotic dependence. The BUNAVAIL™ product features BDSI's novel BEMA® drug delivery technology, together with two well-known active ingredients, buprenorphine hydrochloride and naloxone hydrochloride dihydrate. BUNAVAIL™ is a mucoadhesive buccal film dosage unit. To use the product, a patient will place it on the inside of his cheek, where it will adhere and deliver drug through the mucosal lining of the cheek.

20. The BUNAVAIL™ product can be used as a therapeutic alternative to Suboxone® film. The BUNAVAIL™ product must be specifically prescribed by a physician, and is not a "generic" version of Suboxone®.

21. The FDA approved BDSI's BUNAVAIL™ product on June 6, 2014. BDSI announced via press release on June 6, 2014 that it would launch the BUNAVAIL™ product late in the third quarter of 2014.

22. BDSI is currently in the final stages of preparing to launch the BUNAVAIL™ product commercially, and expects that BUNAVAIL™ will be available to patients within less than a month.

C. Previous Litigation By Defendants Against BDSI

23. In addition to the various PTO proceedings described above, there is a lengthy history of litigation that Defendants have asserted against BDSI.

1. The District of New Jersey Litigation

24. On November 2, 2010, MonoSol filed suit in the District of New Jersey (District of New Jersey Civil Action No. 3:10-cv-05695-FLW-DEA) against BDSI and its strategic

partner, Meda Pharmaceuticals Inc., for alleged infringement of United States Patent No. 7,824,588 (the "'588 Patent") by another product developed by BDSI, Onsolis®. MonoSol later amended its complaint to assert U.S. Patent Nos. 7,357,891 (the "'891 Patent") and 7,425,292 (the "'292 Patent"). BDSI requested that the PTO reexamine each of the '588 Patent, the '891 Patent, and the '292 Patent, and the PTO instituted reexaminations.

25. Following BDSI's requests for reexamination of each of the asserted patents, BDSI requested that the District of New Jersey stay the litigation pending the resolution of the reexamination proceedings, and the District Court granted that request, staying the action in its entirety. The PTO has now issued reexamination certificates for the '292 Patent and the '891 Patent, substantially narrowing their claims. A right of appeal notice rejecting all claims of the '588 Patent issued on January 23, 2013. MonoSol appealed to the PTAB on February 22, 2013. On April 17, 2014, the PTAB confirmed rejection of all claims of the '588 patent. MonoSol did not take a further appeal. On August 5, 2014, the PTO issued a Certificate of Reexamination cancelling all claims of the '588 Patent.

26. On September 17, 2014, MonoSol requested that the District of New Jersey lift the stay that is currently in place. As a result of that request, the Court scheduled a status teleconference for October 27, 2014.

2. RBP's Citizen Petitions

27. On December 2, 2011 and on August 12, 2013, RBP filed Citizen Petitions with the FDA seeking to require new drug applicants seeking approval to market a product containing buprenorphine and naloxone to use the application for Suboxone® film as a reference point, rather than the application for the older, now-discontinued Suboxone® tablet. If RBP's Citizen Petitions were granted, new drug applicants relying on the Suboxone® film application as a point of reference would have had to provide patent certifications to the FDA and RBP, and

otherwise followed what is traditionally referred to as the Hatch Waxman process, which could have delayed FDA approval and the launch of BUNAVAIL™.

28. The FDA denied RBP's petitions on September 18, 2013.

3. Defendants Initiated a Premature Suit in this Court

29. On October 29, 2013, RBP, RBP UK and MonoSol filed a Complaint for Patent Infringement in the Eastern District of North Carolina (Civil Action No. 5:13-760-BO), alleging that BUNAVAIL™ – a product that, at the time, had neither received FDA approval nor been marketed by BDSI – infringed the '832 Patent pursuant to 35 U.S.C. § 271(e)(2). RBP, RBP UK, and MonoSol also sought a declaratory judgment that BUNAVAIL™ would, if marketed, infringe the '832 Patent pursuant to 35 U.S.C. § 271(a)-(c).

30. On December 13, 2013, BDSI moved to dismiss the Complaint for several reasons, including the fact that (i) the plaintiffs (in Civil Action No. 5:13-760-BO) failed to state a claim for patent infringement pursuant to 35 U.S.C. § 271(e)(2), and (ii) the plaintiffs' (in Civil Action No. 5:13-760-BO) claim for declaratory judgment was not ripe and therefore failed to invoke the Court's subject matter jurisdiction. (D.I. 18 in Civil Action No. 5:13-760-BO).

31. On May 21, 2014, this Court dismissed Civil Action No. 5:13-760-BO after concluding that the declaratory judgment claims were premature, and that RBP, RBP UK, and MonoSol had failed to state a so-called Hatch-Waxman claim for patent infringement under 35 U.S.C. § 271(e)(2). RBP, RBP UK, and MonoSol did not appeal the dismissal of Civil Action No. 5:13-760-BO.

D. Defendants Have Indicated An Intent to Sue BDSI Yet Again

32. Defendants have stated publicly that they will sue BDSI upon launch of the BUNAVAIL™ product. During Reckitt Benckiser Group's investor presentation on July 28, 2014, a public event, Shaun Thaxter, the Chief Executive Officer of RBP, represented in

reference to BDSI that "of course the minute they launch [the BUNAVAIL™ product], we will sue them for patent infringement...we are going to be aggressive about that and uncompromising." Upon information and belief, RBP and MonoSol are aligned in their plans to sue BDSI, and consistent with their past actions, RBP UK, RBP, and MonoSol are planning to jointly sue BDSI.

33. The FDA approved the BUNAVAIL™ product on June 6, 2014. At that time, BDSI announced via press release that it would launch the BUNAVAIL™ product late in the third quarter of 2014.

34. Prior to FDA approval and through the present, BDSI has made substantial preparations for the launch of BUNAVAIL™. For example, on May 17, 2014, BDSI announced via press release a commercialization agreement with Quintiles to support the launch of BUNAVAIL™ in the United States. Through this and other steps, BDSI has readied itself for the commercial launch of BUNAVAIL™, which is presently scheduled to occur in less than a month.

35. As noted above, BDSI's commercial launch of the BUNAVAIL™ product is imminent. Based on Defendants' previous actions and statements, BDSI has a reasonable apprehension of being sued by Defendants for patent infringement of the Patents-in-Suit.

COUNT I

(Declaratory judgment of non-infringement and invalidity of the '832 Patent against all Defendants)

36. BDSI incorporates the allegations of paragraphs 1-35 above as if set forth herein in full.

37. The claims of the '832 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 101, 102, 103, and 112.

38. BDSI's commercial manufacture, use, sale, offer for sale, and/or importation of the BUNAVAIL™ product will not infringe any valid claim of the '832 Patent.

39. An actual and justiciable controversy exists between BDSI and all Defendants with respect to the '832 Patent, and BDSI is entitled to a declaratory judgment that the '832 Patent is invalid and not infringed by BDSI.

COUNT II

(Declaratory judgment of non-infringement and invalidity of the '080 Patent against MonoSol and RBP)

40. BDSI incorporates the allegations of paragraphs 1-39 above as if set forth herein in full.

41. The claims of the '080 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 *et seq.*, including but not limited to §§ 101, 102, 103, and 112.

42. BDSI's commercial manufacture, use, sale, offer for sale, and/or importation of the BUNAVAIL™ product will not infringe any valid claim of the '080 Patent.

43. An actual and justiciable controversy exists between BDSI and the MonoSol and RBP Defendants with respect to the '080 Patent, and BDSI is entitled to a declaratory judgment that the '080 Patent is invalid and not infringed by BDSI.

COUNT III

(Declaratory judgment of non-infringement and invalidity of the '378 Patent against MonoSol and RBP)

44. BDSI incorporates the allegations of paragraphs 1-43 above as if set forth herein in full.

45. The claims of the '378 Patent are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100 et seq., including but not limited to §§ 101, 102, 103, and 112.

46. BDSI's commercial manufacture, use, sale, offer for sale, and/or importation of the BUNAVAIL™ product will not infringe any valid claim of the '378 Patent.

47. An actual and justiciable controversy exists between BDSI and the MonoSol and RBP Defendants with respect to the '378 Patent, and BDSI is entitled to a declaratory judgment that the '378 Patent is invalid and not infringed by BDSI.

DEMAND FOR JURY TRIAL

48. BDSI hereby requests a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, BDSI respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the claims of the '832 Patent are invalid;

B. Declare that BDSI's commercial manufacture, use, sale, offer for sale, and/or importation of the BUNAVAIL™ product will not infringe any valid claims of the '832 Patent;

C. Declare that the claims of the '080 Patent are invalid;

D. Declare that BDSI's commercial manufacture, use, sale, offer for sale, and/or importation of the BUNAVAIL™ product will not infringe any valid claims of the '080 Patent;

E. Declare that the claims of the '378 Patent are invalid;

F. Declare that BDSI's commercial manufacture, use, sale, offer for sale, and/or importation of the BUNAVAIL™ product will not infringe any valid claims of the '378 Patent;

G. Award BDSI its costs and reasonable attorneys' fees to the extent permitted by law; and

H. Award BDSI such other and further relief as the Court deems just and proper.

Dated: September 20, 2014 **MYERS BIGEL SIBLEY & SAJOVEC, P.A.**

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